AUG 1 6 2001

K 010547

510 (K) SUMMARY

As Required by the Safe Medical Devices Act of 1990

Apex Dental Materials, Inc.
603 Berkley Court
Schaumburg, IL. 60194
Phone: (847) 490-1014

510 (K) Submission Date: February 22, 2001

Contact Person: Scott Lamerand

Device Name:

Trade Name:	Vertex Sealant L/C Orthodontic Sealant
Common Name:	Orthodontic Bracket Adhesive
Classification Name:	Bracket Adhesive Resin and Tooth Conditioner, per 21 CFR parts 872.3750

Classification:

Regulatory Class:	II
Product Code:	DYH

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE

Light Bond Bonding Resin™

Light Bond Bonding Resin™ (Reliance Orthodontic Products) is a single paste composite orthodontic bonding system utilizing a BisGMA based resin sealant, between the etched enamel tooth surface and the orthodontic bonding paste. Its physical properties are similar to the applicant device and uses are identical. Like the applicant device, Light Bond Bonding Resin™ is one component used in conjunction with a complete orthodontic bonding system. It hardens by a light cure polymerization mechanism employing a light initiator, and a chemical activator.

Summary continued:

DESCRIPTION OF APPLICATION DEVICE

VERTEX SEALANT L/C ORTHODONTIC SEALANT

Vertex Sealant L/C Orthodontic Sealant is designed to provide an orthodontist with a high strength, rapid cure, resin based sealant material for use in achieving the retention of metal, ceramic (and/or plastic) orthodontic brackets to etched-enamel tooth surfaces. The product is a BisGMA based resin used between an etched enamel surface and an orthodontic bonding paste. The product is cured via photo-initiated free radical polymerization. When properly employed, the sealant is designed to maintain tooth-bonding paste adhesion for the duration of the orthodontic treatment. Vertex Sealant L/C Orthodontic Sealant is designed to be marketed as a stand alone product but can be made available in kit form including Vertex Etchant (K010849) and Vertex L/C Orthodontic Direct Bonding Paste (K010544).

INTENDED USES OF APPLICANT DEVICE

Vertex Sealant L/C Orthodontic Sealant is indicated to provide adhesion between an etched enamel substrate surface and a metal, ceramic (and/ or plastic) orthodontic bracket when using a composite bonding paste, such as Vertex L/C Orthodontic Direct Bonding Paste (K010544)

Summary continued:

PERFORMANCE CHARACTERISTICS and CONCEPTS

Vertex Sealant L/C Orthodontic Sealant has similar handling to the Light Bond Bonding Resin™. From the physical testing observations and analysis, including shear bond strength, diametral tensile strength and compressive strength, we suggest that Vertex Sealant L/C is substantially equivalent to Light Bond Bonding Resin™ (Reliance Orthodontic Products). Along with this we would suggest the individual components of Vertex Sealant L/C are long time industry standards and are utilized in numerous orthodontic bracket-bonding systems currently marketed in the United States (see Confidential Formulation Details on page 5).

Equivalent Product and Manufacturer	Corresponding 510(k) Numbers
Light Bond™ (Reliance Orthodontic Products)	K880793

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2001

Mr. Scott Lamerand
Apex Dental Materials, Incorproated
603 Berkley Court
Schumburg, Illinois 60194

Re: K010547
Trade/Device Name: Vertex Sealand L/C Orthodontic Sealant
Regulation Number: 872.3200
Regulatory Class: II
Product Code: KLE
Dated: August 3, 2001
Received: August 3, 2001

Dear Mr. Lamerand:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010547

Indications for Use

510(K) Number (if known): K010547

Device name: Vertex Sealant L/C Orthodontic Sealant

Indications For Use:

Vertex Sealant L/C Orthodontic Sealant is designed to provide an orthodontist with a high strength, rapid cure, resin based sealant material for use in improving the retention of metal (and/or plastic) orthodontic brackets to etched-enamel tooth surfaces. The product is a BisGMA based resin used between an etched enamel surface and an orthodontic bonding paste. The product is cured via photo-initiated free radical polymerization. When properly employed, the sealant is designed to maintain tooth-bonding paste adhesion for the duration of the orthodontic treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRL, Office of Device Evaluation (ODE)

Prescription use X
(Per 21 CFR 801.109

OR

Over- The- Counter Use

(Optional Format 1-2-96)

MPCaldwell for MSK

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K010547